REMARKS

Claims 1-63 of which claims 1, 49, 62 and 63 are independent claims are presently pending. All the claims are rejected in the Office Action mailed December 2, 2004.

Claims 1-25, 27-29, 36-38, 40, 46, and 62 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. US 6,468,215 to Sarvazyan et al in view of US 5,483,965 (US 965) to Wiener et al, or in the alternative, under §103(a) as unpatentable over Sarvazyan in view of Wiener and any one of US 5,895,364 to Donskoy or US 5,806,520 to Berger et al.

Independent claims 1 and 62 claim using acoustic energy that is propagated *substantially transverse* to a skeletal structure to determine the structure's age.

In rejecting claims 1-25, 27-29, 36-38, 40, 46, and 62 over Sarvazyan in view of Wiener, the Examiner submits that "Sarvazyan et al uses both longitudinal and flexural components of bone measurements to assess skeletal age. Since Wiener et al ... note that both velocity and attenuation measurements for cortical bone may be made using a single transducer and reflective member (paired members are only used as an expedient to obtain absolute values) it would have been obvious to effect the Sarvazyan expedient to obtain cortical flexural velocity and attenuation in this fashion".

In addition, apparently in support of and completion of the above argument, the Examiner has argued in his "Response to Amendment Arguments" that the Wiener reference has been added "to emphasize that *transverse* reflective measurements across the bone were accepted for determining velocity and attenuation within the bone, whereupon the Examiner is asserting that it would have been obvious to perform *cortical velocity/attenuation* measurement in a transverse fashion". (Italics added.)

Applicant respectfully traverses.

The Examiner appears to assert that "Sarvazyan et al uses both longitudinal and flexural components of bone measurements to assess skeletal age" in order to establish in Sarvazyan a nexus between skeletal age and "flexural components". Presumably, the nexus is necessary in order to make application of Wiener to Sarvazyan palatable, since, whereas Sarvazyan specifically differentiates between longitudinal and flexural sound waves and their applications, *Wiener does not*. Stating that Sarvazyan uses both longitudinal and flexural components presumably enables measurements, such as the transverse measurements proposed by Wiener that do not differentiate between longitudinal and flexural components, to be "obvious" for use, when combined with

Sarvazyan, with regard to skeletal age.

However, applicant has argued in response to the Examiner's previous office action dated March 9, 2004 that Sarvazyan does not teach using flexural waves for determining age and in particular that "Sarvazyan et al teaches away from using flexural sound waves for determining bone age. Column 3 lines 46-50 specifically cite *longitudinal waves as useable to determine skeletal age. Nowhere does the patent note that flexural waves may be used for determining skeletal age.* The citation of longitudinal waves and the omission of a similar citation with respect to flexural waves, teaches away from using flexural waves for determining skeletal age." (Italics added.) Applicant notes that the Examiner has not addressed the above argument as required by MPEP 707.07(f) and Examiner Note 7.37, and unless properly addressed and, if possible, rebutted, the argument must be considered viable and submissions contrary thereto not cogent.

In view of the above, since Sarvazyan does not teach flexural measurements for determining age, the Examiner's argument for a nexus between Sarvazyan and Wiener, is not established.

Additionally, as presented in the applicant's last response, in transverse measurements, such as those described in Wiener, sound waves travel not only through cortical bone but also through *trabecular* bone. As a result, transverse measurements provide information different from that of measurements along bone and it is not obvious to use or adapt the methods of one to provide the different information that the other provides. Therefore, it is decidedly *not obvious* "to perform cortical velocity attenuation measurements in a transverse fashion" as claimed by the Examiner. (Applicant notes that a similar argument, presented with respect to Berger et al in the previous response has also not been addressed by the Examiner.)

In support of applicant's arguments above, it is noted that the only example of transverse measurements detailed by Wiener, are measurements transverse to the heel. With regard to such measurements and techniques, Sarvazyan notes "There is a numerical superiority of heel QUS techniques over long bone QUS allowing good opportunity to evaluate density of *trabecular structure* in osteoporosis, but limiting QUS application for other sites of the skeleton, *thereby hampering* comprehensive evaluation of osteoporosis and *monitoring of bone growth and ossification during childhood.*" (column 2 lines 46-52, italics added.) The preceding quote from Sarvazyan, indicates that while heel QUS techniques, such as techniques described in Wiener, provide information regarding

trabecular bone they are not suitable for "monitoring of bone growth and ossification during childhood". Sarvazyan therefore explicitly teaches away from and discourages combining any of the methods of Wiener with those of Sarvazyan.

In view of the above arguments, individually and/or in combination, applicant submits that there is no way Sarvazyan and Wiener can be combined, nor motivation to do so, to provide the invention claimed in claims 1 and 62. Sarvazyan and Wiener therefore do not provide basis for a prima facie obviousness rejection of claims 1 or 62.

The Examiner alternatively argues, "since Sarvazyan et al suggest using attenuation and velocity to assess gestational and or developmental ages of bone, it would have been obvious to extend the Wiener et al pathology applicability to skeletal age (deficiency) measurement".

The Examiner's alternative argument is traversed for some of the same reasons given above for traversing the Examiner's first argument, in particular:

1) because transverse measurements provide information different from that of measurements along bone described by Sarvazyan for age determination and it is not obvious to use or adapt the methods of one to provide the different information that the other provides; and

2) in view of Sarvazyan's statement with regard to lack of suitability of heel QUS techniques for monitoring bone growth and ossification during childhood.

In a further alternative, "Donskoy is cited for its col. 1 teaching that flexural measurements mean across or transverse bone and longitudinal means along bone. Hence Sarvazyan et al are referring to across as well as along bone and are compositing the two types of measurements in their analysis by virtue of this art supplied definition."

The words "flexural" and "longitudinal" are recited in only three places in column 1. In none of the recitations is a flexural measurement defined as meaning "across" or "transverse" to bone or a longitudinal measurement as meaning "along" bone. Applicant has also searched the remainder of Donskoy for the definitions noted by the Examiner, but has failed to locate such definitions. The three relevant recitations in column 1 are quoted below.

"Subsonic techniques for determining the in vivo properties of bone, known as impedance and resonance methods are based on measurement of the response of a bone to a flexural wave excitation in the frequency range 200 to 1000 Hz." (column 1 lines 32-36)

"Interpretation of subsonic measurement of flexural vibration of bone is also a

difficult task and to a great extent, depends upon a corresponding mathematical model of the test object." (column 1 lines 47-50)

"A non-invasive, nonhazardous and cost effective infrasound resonance method for the quantitative measurement and monitoring of bone quality has now been developed involving the measurement of the rigid body longitudinal resonance of a bone." (column 1 lines 53-57)

With respect to the further alternative rejection based on Berger, the Examiner submits that it would have been obvious to adapt Berger's technique of "using transverse through-transmission with opposed transducer faces" for long bone scanning in Sarvazyan et al "in order to accurately know the exact path distance which the ultrasound takes via this caliper style transducer separation setting". The Examiner's argument repeats the rejection based on Berger put forth by the Examiner in the last office action. An argument in traverse of the rejection was submitted by the applicant in the response to the office action but never addressed by the Examiner.

As argued in the last response, and in the present response, Sarvazyan et al, by providing bone measurements along the bone probes the characteristics of the cortical region of a bone. In transverse measurements, such as those described in Berger et al, and as noted above with respect to Wiener, sound waves travel not only through cortical bone but also through trabecular bone. As a result, transverse measurements provide information different from that of measurements along bone and it is not obvious to use or adapt the methods of one to provide the different information that the other provides.

In addition, Sarvazyan et al's apparatus, since it constrains the path of ultrasound to extend between two well defined points on the skin of the patient along the bone and measures thickness of soft tissue using reflected ultrasound, provides an accurately defined path for ultrasound along bone. The patent notes (column 5 lines 10-19) that the apparatus effectively eliminates contribution of the soft tissue to its ultrasound measurements by measuring the thickness of soft tissue. The patent must therefore be understood to teach a satisfactory method for providing an accurate propagation path for ultrasound in bone and to reject a need or motivation for using additional methods to provide such a path. Furthermore, Berger et al uses a method for correcting for soft tissue in determining a bone propagation path for ultrasound similar to that already promulgated in Sarvazyan et al, i.e. reflecting ultrasound from the surface of bone (column 7 line 60 - column 8 line 4) to determine soft tissue thickness. It therefore appears in this respect that

even if there were motive for providing a method for improving measurement of bone propagation path in Sarvazyan, Berger et al would not be the source for such a method.

Claims 49-51, 52-57 are rejected under U.S.C. §103(a) as being unpatentable over Sarvazyan et al and Wiener et al, further in view of Berger et al. The only independent claim among these claims is claim 49 which recites "an acoustic transmitter and an acoustic receiver positioned facing each other so that an ossification-actuated skeletal structure may be positioned between them". The receiver is used to acquire acoustic signals transmitted from the transmitter transverse to the skeletal structure to the receiver. The acoustic signals are used to estimate bone age.

Applicant traverses the combination of Sarvazyan and Wiener and/or Berger for the same reasons noted in the traverse of the rejection of claims 1-25, 27-29, 36-38, 40, 46, and 62.

Claim 63 is rejected 35 U.S.C. §103(a) as being obvious over Sarvazyan and Wiener, further in view of US 5,197,475 to Antich et al.

Claim 63 claims a method of determining bone age comprising: measuring a first acoustic velocity through a bone in a direction transverse to the bone; measuring a second acoustic velocity along a length of the bone; determining a ratio between the first and second acoustic velocities; and using the ratio to determine bone age.

The combination of Sarvazyan and Wiener is traversed as above. With respect to Antich et al, the patent mentions a ratio between velocities in only two places (column 14 lines 23-24 and column 14 lines 49-52). The ratios refer to ratios between results of measurements of velocity using different techniques, a reflection technique and a transmission technique, and are used to compare the measurements and determine a degree to which they are correlated.

In column 14 lines 23-24 the ratio refer to measurements carried out on "laboratory materials which were believed to be essentially isotropic and homogeneous (column 13 lines 22-24). The measurements on the laboratory materials certainly do not apply in any way to claim 63.

In column 14 lines 49-52 the ratio refers to measurements carried out on cortical bone specimens having machined and lapped surfaces (column 13 lines 42-50). A difference of the ratio from 1 is ascribed to the measurements of transmission and reflection velocities being acquired at different frequencies and additionally because of "material heterogeneities structural geometry and density variations" (column 14 lines 47-

61). There is no attempt in the patent to correlate the ratio with age or intimate such a correlation. Indeed, there does not seem to be any indication that the ratio is useable for anything other than to show that the measurements correlate with each other. Applicant therefore submits that the Examiner has not shown how to combine Antich et al with the other references mentioned in the rejection to provide the invention of claim 63 nor provided any motivation to do so and that therefore the reference is not useable to support a prima facie obviousness rejection of the claim.

In view of the above, the applicant submits that all the independent claims of the application are patentable over the cited art and that claims dependent on the independent claims are patentable through their dependence or as a result of patentable material that they contain.

Applicants respectfully point out that a First Supplementary Information Disclosure Statement was filed on January 27, 2003 (including a 2-page PTO-1449 form) and a Second Supplementary Information Disclosure Statement was filed on June 23, 2003 (including a 1-page PTO-1449 form). In the Office Action dated March 9, 2004, the Examiner returned PTO-1449 forms without initialing pages labeled 5 and 6. Applicants are resubmitting the PTO-1449 forms and respectfully request that the items listed thereon be initialed by the Examiner to ensure that they appear on the face of the patent that may issue on the present application. Applicants assume that the art has already been considered by the Examiner in accordance with MPEP §609.

An allowance is respectfully anticipated.

Respectfully submitted,
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